

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: ACTOS DIRECT PURCHASER
ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:
ALL ACTIONS

Master File No. 1:15-cv-03278-RA-RLE

MEMORANDUM OF LAW IN SUPPORT OF
MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

The direct purchaser plaintiffs (“direct purchasers”), through counsel, move, pursuant to Rule 15 of the Federal Rules of Civil Procedure and this Court’s October 13, 2015 order, for leave to file an amended complaint. A copy of the proposed second consolidated class action complaint and jury demand is attached hereto as Exhibit 1.

I. PROCEDURAL BACKGROUND

Two different plaintiff groups filed antitrust class actions alleging that the defendants¹ implemented an anticompetitive scheme to forestall would-be generic competition to unlawfully extend their monopolies in the Actos (pioglitazone hydrochloride) and Actoplus met (pioglitazone hydrochloride and metformin) markets. In December 2013, the end-payor plaintiffs filed *In re Actos End-Payor Antitrust Litigation*, No. 13-cv-9244 (S.D.N.Y.) (the “*Actos End-Payor Case*”). In April 2015, the first direct purchaser action was filed, and on June 3, 2015 the Court consolidated two direct purchase actions, *In re Actos Direct Purchaser Antitrust Litigation*, No. 15-cv-3278 (S.D.N.Y.) (the “*Actos Direct Purchaser Case*”).²

¹ Defendants are Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively, “Takeda”), Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively, “Mylan”), Actavis plc f/k/a Actavis, Inc. and Watson Laboratories, Inc. (collectively, “Actavis”), Sun Pharmaceutical Industries Limited as successor-in-interest to Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., and Ranbaxy Pharmaceuticals, Inc. (collectively, “Ranbaxy”), and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, “Teva”).

² See Compl., ECF No. 1; Consolidation Order, June 3, 2015, ECF No. 13.

On June 4, 2015, the direct purchasers filed a Consolidated Class Action Complaint (the “Consolidated Complaint”).³ On June 5, 2015, at the defendants’ request, the Court adjourned defendants’ deadline to answer or otherwise respond to the Consolidated Complaint until 35 days from the filing of this Court’s decision on the then-pending motions to dismiss in the *Actos* End-Payor Case.⁴

On September 22, 2015, this Court entered an Opinion & Order granting the motions to dismiss in the *Actos* End-Payor Case and dismissed those consolidated actions in their entirety.⁵

On October 6, 2015, this Court ordered the parties in the *Actos* Direct Purchaser Case to appear by teleconference to discuss the import of its decision dismissing the *Actos* End-Payor Case.⁶ At the teleconference on October 13, 2015, the Court indicated its inclination to grant the direct purchasers leave to amend their complaint, and provide the defendants 45-days to either (i) oppose the motion to amend or (ii) move to dismiss the amended pleading, and provided the parties 45 days to file an opposition and 30 days to file a reply, as applicable. On November 12, 2015, the Court granted the direct purchasers’ unopposed motion for an extension of time to file their motion for leave to amend their pleadings, to November 16, 2015. To date, defendants have not yet responded to, or otherwise moved against, the direct purchasers’ Consolidated Complaint.

³ Consol. Class Action Compl., ECF No. 14.

⁴ Order, June 4, 2015, ECF No. 17.

⁵ *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244, 2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015).

⁶ Order, Oct. 6, 2015, ECF No. 37.

II. ARGUMENT

A. Amendments to the Complaint

Plaintiffs file this motion seeking leave to file an amended complaint in the form attached hereto. *See* proposed Second Consolidated Class Action Complaint and Jury Demand, attached as Exhibit 1. As set forth in more detail therein, this amended complaint:

1. Sets forth a stand-alone monopolization claim against Takeda under § 2 of the Sherman Act for its wrongful listing in the Orange Book of the '584 of '404 patents, which is independently actionable regardless of whether the subsequent pacts made with the generic defendants are themselves actionable.
2. Pleads, with specificity, how and in what ways Takeda's wrongful listing of the '584 of '404 patents was unlawful and independently actionable.
3. Pleads, with specificity, how defendants entered into a March 2010 pact and a December 2012 pact as part of a scheme to forestall generic entry of Actos, whether as part of an unlawful reverse payment agreement actionable under *Actavis*⁷ or as an unlawful allocation scheme actionable under traditional rule of reason analysis.
4. Pleads, with respect to the March 2010 pact, a reasonable estimate of the size of the payments made by Takeda to the generics, and how such payments are large and unjustified under *Actavis*.
5. Pleads, with specificity, how the coordination clauses contained in the settlements with the generic defendants as part of the March 2010 and December 2012 pacts, are, in the circumstances of this case, anticompetitive.
6. Pleads, with specificity, how each of the authorized generic agreements with the generic defendants are anticompetitive, and that none of those agreements have any procompetitive benefits.
7. Addresses the court's causation ruling, pleading with specificity how each of the actions described above – the wrongful Orange Book listings and the unlawful March 2010 pact and the December 2012 pacts – caused the anticompetitive harms alleged.

⁷ *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

B. Legal Standard

Rule 15 of the Rules of Civil Procedure requires leave to amend be “freely given when justice so requires.”⁸ The purpose of Rule 15’s “permissive standard”⁹ is “to provide maximum opportunity for each claim to be decided on its merits.”¹⁰ Accordingly, a motion to amend should only be denied upon a showing of “undue delay, bad faith, futility of amendment, and perhaps most important, the resulting prejudice to the opposing party.”¹¹ None of these factors compel the denial of the direct purchasers’ proposed amendment.

Although an amendment may be prejudicial to a nonmoving party if it “would require the opponent to expend significant additional resources to conduct discovery and prepare for trial or significantly delay the resolution of the dispute,”¹² “time, effort and money . . . expended in litigating” alone does not constitute prejudice.¹³ Permitting an amendment to a complaint while the litigation is still in the pleadings stage does not prejudice a defendant.¹⁴ Here, the

⁸ *Wight v. BankAmerica Corp.*, 219 F.3d 79, 91 (2d Cir. 2000); Fed. R. Civ. P. 15.

⁹ *Williams, v. Citigroup Inc.*, 659 F.3d 208, 213 (2d Cir. 2011).

¹⁰ *Slayton v. Am. Express Co.*, 460 F.3d 215, 228 (2d Cir. 2006) (internal quotations omitted).

¹¹ *State Teachers Ret. Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir. 1981); *Block v. First Blood Assocs.*, 988 F.2d 344, 350 (2d Cir. 1993) (“[T]he rule in [the Second] Circuit has been to allow a party to amend its pleadings in the absence of a showing by the nonmovant of prejudice or bad faith”).

¹² *Ruotolo v. City of New York*, 514 F.3d 184, 192 (2d Cir. 2008) (quoting *Block v. First Blood Assocs.*, 988 F.2d 344, 350 (2d Cir. 1993)) (internal quotation marks omitted).

¹³ *Block*, 988 F.2d at 351; cf. *Krumme v. WestPoint Stevens Inc.*, 143 F.3d 71, 88 (2d Cir. 1998) (“[A] proposed amendment ... [is] especially prejudicial ... [when] discovery ha[s] already been completed and [the non-movant] ha[s] already filed a motion for summary judgment” – factors not implicated by the present motion.).

¹⁴ See, e.g., *Maddox v. Fowler*, No. 14-cv-1068, 2015 WL 4366222, at *6 (N.D.N.Y. July 16, 2015) (“The Court finds that, because the motion to amend has been made at a relatively early stage of the proceeding (i.e., less than two months after Defendants were served with the complaint and before discovery has commenced), and Defendants were on notice of the facts supporting the proposed amended complaint, Defendants will not suffer undue prejudice.”); *Camota v. City of New York*, No. 09-cv-2545, 2013 WL 867199, at *2 (E.D.N.Y. Mar. 7, 2013) (“Given that the parties are still at the pleadings stage, defendants are not prejudiced by permitting plaintiff to file a third amended complaint.”); *Ellis v. Jean*, No. 2011 WL 6368555, at *9 (S.D.N.Y. Dec. 6, 2011) (“Discovery has not yet commenced in this case. In addition, Defendants have given no indication that the amendments would impact the timeliness of the resolution of this dispute Thus, the Court finds that Plaintiffs’ proposed amendments would not work prejudice on Defendants, and Plaintiffs’ motion for leave to amend their complaint is granted.”); *Arc/Connecticut v. O’Meara*, No. 01-cv-1871, 2002 WL 31106383, at *3 (D. Conn. 2002) (amended complaint filed soon after action was commenced broadening the scope of the case resulted in no prejudice); *United States v. Felicissimo*, No. 90-cv-4094, 1994 WL 163997 (S.D.N.Y. Apr. 22, 1994) (“[N]o undue prejudice to the defendant would result from the Court granting plaintiff leave to file this Supplemental Complaint, inasmuch as discovery has only recently commenced, and no trial date has been set.”).

proceedings are in the very early stages: the defendants have not yet responded to the direct purchasers' initial pleadings, and the parties have not commenced discovery. Under these circumstances, the defendants will suffer no prejudice as a result of the direct purchasers' proposed amendment.

Any alleged futility of amendment "is to be judged by the same standards as those governing the adequacy of a filed pleading."¹⁵ Accordingly, leave to amend a pleading on the grounds of futility is appropriate only if "the proposed amendment fails to state a legally cognizable claim or fails to raise triable issues of fact."¹⁶ Where a proposed amendment cures prior deficiencies, leave to amend should be granted.¹⁷

Here, the proposed Second Consolidated Class Action Complaint and Jury Demand addresses the issues raised by the Court in its decision dismissing the *Actos* End-Payor Case, and otherwise cures deficiencies that may have been present in the Consolidated Complaint. As indicated above and explicated in the attached, the amended complaint, among other things, alleges new and clarifying facts demonstrating: (i) an independently actionable Section 2 claim against Takeda arising from its wrongful listing in the Orange Book of the '584 and '404 patents; (ii) how the at-issue reverse payments were large and unjustifiable under *Actavis*; and (iii) that, regardless of any reverse payments, defendants' conduct is also actionable as an unlawful allocation scheme under traditional rule of reason analysis.

III. CONCLUSION

For the foregoing reasons, direct purchasers respectfully request this Court grant plaintiffs leave to file the second consolidated class action complaint and jury demand.

¹⁵ *Anderson News, L.L.C. v. Am. Merdia, Inc.*, 680 F.3d 162, 185-86 (2d Cir. 2012).

¹⁶ *AEP Energy Servs. Gas Hldg. Co. v. Bank of Am., N.A.*, 626 F.3d 699, 726 (2d Cir. 2010) (citing *Milanesi v. Rust-Oleum Corp.*, 244 F.3d 104, 110-11 (2d Cir. 2001)).

¹⁷ *Cf. Panther Partners, Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 119 (2d Cir. 2012) (noting that leave to amend is appropriate only where "proposed amendments would fail to cure prior deficiencies or to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure").

Dated: November 16, 2015

Respectfully Submitted,

/s/ **Thomas M. Sobol**

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: November 16, 2015

/s/ **Thomas M. Sobol**

Thomas M. Sobol